

Ortholution Co.,Ltd.

K052968

SEP - 8 2006

510 (k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: September 26, 2005

1. Company making the submission:

	Company
Name	Ortholution Co., Ltd.
Address	207 Dunchon B/D., #416-1 Seongnae-Dong, Gangdong-Gu, Seoul, Korea
Phone	
Fax	+ 82 2-483-1212
Contact	+ 82 2-478-0735
Internet	J. M. Kim / president Doldol22@netian.com

2. Device:

Proprietary Name – ORLUS mini screw

Common Name – Small bone screw

Classification Name – Endosseous dental implant

3. Predicate Device:

Ortholution Co., Ltd. ORLUS Mini Screw K050568

4. Classifications Names & Citations:

21CFR 872.3640, DZE, Endosseous dental implant, Class2

5. Description:

ORLUS mini screw is intended to provide a fixed anchorage for orthodontic movement of teeth. It is 1.4 - 1.8 mm in diameter and range from 5-13 mm in total length and is made of Titanium 6Al-4V alloy. There are dual heads in the screw with which a wire can be hung to fix the maxilla and mandible. It is used temporarily and is removed after orthodontic treatment has been completed. It is supplied sterile and intended for single use only.

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Ortholution Co.,Ltd.

6. Indication for use:

The ORLUS mini screw is intended for use as temporary anchor for orthodontic treatment.

7. Contra-indications:

- 1) Osteoporosis
- 2) Advanced diabetes
- 3) Metal allergies

8. Review:

ORLUS mini screw has the same device characteristics, material, design and intended use as the predicate device.

ORLUS mini screw has been subjected to product validations prior to release.

Appropriate safeguards have been incorporated in the design of ORLUS mini screw.

9. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Ortholution Co., Ltd. concludes that ORLUS mini screw is safe and effective and substantially equivalent to the predicate device as described herein.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2006

Ortholution Company, Limited
C/O Ms. Cathryn N. Cambria
Consultant
Arkin Consulting Group, LLC
5536 Trowbridge Drive
Atlanta, Georgia 30338

Re: K052968
Trade/Device Name: ORLUS Mini Screw
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: August 24, 2006
Received: August 30, 2006

Dear Ms. Cambria:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Ms. Cambria

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu Lin', with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052968

Device Name: ORLUS Mini Screw

Indications for Use: The ORLUS Mini Screw is intended for use as a temporary anchor for orthodontic treatment.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Signature Sign-Off)
Division of Anesthesiology, General Hospital,
Division Control, Dental Devices

510(k) Number: K052968

Page 1 of 1

000016